

205
B1

C

Soft Tissue

Method for Anterior Cruciate Ligament Reconstruction
Field of the Invention

The present invention relates to a method for the reconstruction of the anterior cruciate ligament of a patient. More particularly it relates to such a method in which a tendon graft is used to replace the ruptured anterior cruciate ligament.

Background Art

As is well known the human knee comprises an articulation of the femur, the tibia and the patella. The femur and the tibia are maintained in a condition of stable articulation by a number of ligaments of which the principal ones are the anterior and posterior cruciate ligaments and the lateral ligaments. The rupture of the anterior cruciate ligament is relatively commonly encountered as a result of sporting injury or the like. This rupture leads to knee instability and can be a debilitating injury.

There have been a number of procedures designed to reconstruct the anterior cruciate ligament. Initially, attempts were made to replace the anterior cruciate ligament with tendons harvested from elsewhere in the body. These tendons were connected respectively to the femur and the tibia by staples, screws or the like inserted exteriorly into the bone and forming an external attachment to which the tendon could be connected externally of the bone. In some cases, the tendon passed over the top of one of the femoral condyles before attachment to the femur and in other cases a hole was drilled through the femur from outside the bone into the intercondylar notch. These attempts at anterior cruciate ligament reconstruction had mixed success. The tendon tended to break at its point of connection to the bone, or become loose over time, indicating that the tendon-bone interface was crucial for effective anterior cruciate

These problems led to the use of bone-tendon-bone grafts generally harvested from mid-third patella tendon with a bone block at each end. Each bone block is

10 patella-femoral problems, especially over the mid-third
patella tendon donor site.

15 manufacture a bone/tendon/bone graft similar to a
mid-third patella tendon graft. The present inventors
have found that the bone quality is extremely variable.
This results in poor fixation and poor intra-operative
pull-out strength in some cases. This procedure was also
20 found to be a very demanding surgical procedure, and
therefore difficult to reproduce.

Disclosure of the Invention

25 patient comprising the steps of:-
a) forming a tendon graft from tendon, other soft tissue
or artificial tendon;
b) forming a hole through the patient's femur from a
suitable point in the intercondylar notch therein
30 anteriorly and laterally, the cross-sectional area of at
least an end portion of the hole through the femur
adjacent the intercondylar notch being sufficient to
receive an end of the tendon graft and a suitable screw,
peg or other fixation device having a leading end and a
35 trailing end;

- c) forming a suitably positioned hole through the patient's tibia opening at one end adjacent the cross-sectional medial tibial spine of the tibia of an area sufficient to receive the other end of the tendon graft;
- 5 d) drawing one end of the tendon graft into the enlarged end portion of the hole in the femur and simultaneously or sequentially drawing the other end of the tendon graft into the hole in the tibia;
- 10 e) inserting the leading end of a fixation device into the hole in the femur from the intercondylar notch end thereof until the trailing end of the fixation device is at least adjacent that end of the hole, and the tendon graft is pressed directly and firmly against a sidewall
- 15 of the hole in the femur by the fixation device; and
- f) after tensioning the tendon graft appropriately, securing the other end of the tendon graft to the tibia.

It has been surprisingly found that, even without the presence of a bone block, a screw or other similar

20 fixation device can adequately secure the tendon graft in place in both the femoral hole and the tibial hole. The initial pull out strength is high and with time permanent fixation is achieved through bone ingrowth into the tendon graft.

- 25 In a preferred embodiment of the invention the tendon graft comprises tendon or tendons derived from the hamstring tendons of the patient or from the achilles tendons of cadavers. Most preferably, the tendons are the semitendinosus and gracilis tendons of the patient
- 30 harvested from the same leg as has the deficient anterior cruciate ligament. The invention could be practised using artificial tendon material or other bodily soft tissue such as ligament. Suitable synthetic plastics materials have been proposed for use in biological applications and
- 35 could be used in place of natural tendon.

00557379:005500

5)

15

20

25

30

35

In another aspect the present invention consists in a method for forming a hole in bone comprising the steps of

25 a) drilling a guide hole in the bone;

b) inserting a guide wire into the guide hole, and

c) passing a cannulated rotary awl down the guide wire while causing the awl to rotate to enlarge the guide hole to a desired size by compressing or compacting the bone

30 around the guide hole.

The one end of the tendon graft is preferably drawn into the femoral hole by a suture that is connected to one end of the tendon or tendons and is positioned to extend through the tibial hole, through the knee joint, through the femoral hole and out of the patient's thigh. As the

10

Brief Description of the Drawings

15

Fig. 2 is a perspective view of the harvested tendon prepared as a graft construct;

20

25

Fig. 5 is of an enlarged perspective view of the cannulated awl used in the procedure depicted in Fig. 4 including cross-sectional views along sections A-A and B-B;

30

Fig. 7 is schematic perspective view of drawing the tendon graft through the tibial hole into the femoral hole;

35

placement of a screw to secure the one end of the tendon graft in the femoral hole;

Fig. 9 is a schematic perspective view showing the placement of a screw to secure the other end of the tendon graft in the tibial hole; and

Fig. 10 is a vertical sectional view of a screw positioned in the femoral hole and securing the one end of the tendon graft.

Best Mode of Carrying out the Invention

10 Operating Protocol

The following protocol assumes the operator will be securing the graft 10 on the femoral side 11 from within the joint and on the tibial side 12 externally. The graft 10 consisting of semitendinosus and gracilis tendons 13 and 14 respectively is also assumed.

Preparation

Routine arthroscopy is performed prior to commencement of reconstruction of the anterior cruciate ligament. Portal placement is critical and can be described thus: the anterolateral portal (not shown) is towards the top of the lateral triangle soft spot. It is made with a transverse stab incision, aimed at the intercondylar notch 15. The anteromedial portal 16 is lower than usual, being 1cm above the joint line and at the fat pad reflection, with the blade aimed slightly up and towards the intercondylar notch.

At this time, using the arthroscope in the anterolateral portal, any meniscal repair or excision is carried out as well as any debridement required for adequate visualisation of the joint in general and the notch in particular. Often this requires partial excision of the fat pad and particularly careful clearing of the notch surface of the lateral condyle of the femur. The scar tissue associated with the ruptured cruciate, the stump of the anterior cruciate ligament and the plica

003000:025500

The semitendinosus and gracilis tendons 13 and 14 are then harvested as graft material. This should be done in whatever fashion the operator is comfortable with, however, a single incision 17 approximately 30 millimeters is all that is required. The incision is medial to the tibial tubercle at the level of the pes anserine

10 insertion. The harvesting of the semitendinosus and
gracilis tendons 13 and 14 should result in at least 22cm
of the tendons. Separation of the tendon should occur at
the musculo-tendinous junction. Care should be taken in
harvesting the tendons to ensure the accessory distal
15 insertions of the semitendinosus in particular are divided
and do not divert the harvesting tool into the body of the
tendon.

After the tendons 13 and 14 are cleared of adherent muscle fibers their length should be measured and the mid-point determined, ideally this is 11cm from the distal insertion of the tendons. The broad surface of the semitendinosus 13 is wrapped around the tendon mass using this tendon to give a smooth exterior surface to the graft 10. The two tendons 13 and 14 are then doubled over a No. 5 suture 18 which will subsequently act as a lead pulling suture. With the tendons doubled over this lead suture by a clip on the free end (not shown), a No. 1 ethybond suture 19 is inserted into the folded end. The four strand hamstring tendon complex 10 is sutured with a modified double baseball stitch to hold them together so that they resist damage upon interference fit screw insertion. The femoral insertion end 22 should consist of at least 3 stitches securing the whole of the tendon mass for a length of 20mm. At the free and tibial insertion end 23 of the tendons 10 another suture 21 is used along

approximately 30mm of length, again, in a modified double baseball stitch pattern. The 11cm long 4 strand tendon graft 10 has now been constructed.

5 A mark is now made, using a sterile marking pen, on the tendon graft 30mm distal to the double folded end of the tendon graft complex. This mark is used to ensure the tendon graft will be pulled up sufficiently into the femoral drill hole. The diameter of the tendon graft is now measured at both the proximal and distal ends, using a
10 tube gauge. These diameters are noted for appropriate awl sizing. Any free tissue in the graft 10 which may bunch up and obstruct the passing of the graft 10 through the tibial and femoral drill holes should now be noted and excised.

15 Having taken the graft, the arthroscope 24 is then inserted into a central portal through a stab incision 25 over the patella tendon, just below the inferior pole of the patella (not shown), thereby allowing better visualisation of the back of the notch 15. Often it is
20 found that further clearing of the lateral wall of the notch 15 is required. This should be performed until the capsular attachment is clearly visualised and palpated with a probe.

Femoral Drilling

25 A point 30° from the top of the notch (11 o'clock in a right knee; 1 o'clock in a left knee) and 5mm from the back of the notch 15 on the lateral wall is then identified and indented with a burr. Care must be taken to avoid identifying the ridge of the anterior edge of the
30 original ACL attachment as the back of the notch (resident's ridge). This error will lead to the femoral tunnel being too anterior, compromising graft function. A 4.5mm drill 26 is then passed into the joint through the medial portal 16 and the tip placed in the burr hole while
35 the knee is held at 90° (the use of standard tissue

Holding the drill tip in the shallow hole thus created the knee is pushed into as much flexion as it will achieve. Directing the drill approximately 20° anteriorly and 30° laterally with respect to the femur, a guide hole is then made, with drilling ceasing as soon as the outer cortex is felt to have been pierced. Withdraw the drill 26 and inspect the hole 29 to confirm position by passing the arthroscope deep into the notch.

30 The awl 28 is then removed and a nylon loop
 (not shown) threaded into the eye 31 of the beath pin 27.
 With the loop end held, the pin 27 is drawn out of the
 femur and the free ends of the nylon and drawn through the
 femoral hole 29 and out of the thigh. Smoothing of the
 edge of the femoral hole and debridement of any loose
 35

tissue is now carried out.

The tibial hole is then made with the use of a guide 33. The tip 34 of the guide 33 is passed through the anteromedial portal 16 and placed on a line from the anterior horn of the lateral meniscus to the medial tibial spine and medially, one quarter of the way across the intercondylar notch, that is just medial to the medial tibial spine. The drill guide 33 then passes through the distal skin incision 17 used for the harvesting of the hamstring tendon graft 10 and measures 40-45 mm distal from the cruciate ligament tibial attachment. The 4.5 mm drill 35 is used to establish the line until the cortex of the tibial plateau is reached, whereupon the guide is removed and the drilling completed under direct vision. The final position may be fine tuned by hand, so that the final drill position will abut the medial eminence and remove the anterior cruciate ligament stump. Having achieved satisfactory placement of the 4.5mm drill 35, a 2.0mm guide wire (not shown) is passed into the hole. The guide wire should intersect the PCL near its femoral insertion to indicate correct drill hole placement and alignment. A cannulated awl (not shown but similar to awl 28) of minor diameter equal to that of the tendon graft's distal end can now be introduced over the guide wire. Drilling of the tibial hole 36 should continue up to a marker just distal to the cutting ears. When tibial hole enlargement is completed, the soft tissue at the entry to the joint can be cleared with a shaver.

With the knee at 90° flexion, a pair of grasping arthroscopy forceps (not shown) are then passed through the tibial drill hole until the jaw of the forceps is around the nylon threads previously passed through the joint. The looped end of the thread is then pulled through the tibial drill hole 36. The thread now passes through the tibial and femoral drill holes and is used to

pass the leading graft thread 18. The threads 18 from the tendon graft 18 complex 10 are placed through the lead thread loop and pulled proximally. Using these threads 18, the graft 10 is drawn into the joint and then into the femoral hole 29 until the mark made earlier, 30mm from the doubled end 22 of the graft 10, is at the entrance to the femoral drill hole 29. Care should be taken as the graft 10 is pulled up that the distal insertion of the tendon graft 10 is not preventing the graft from passing up the tibial hole 36. Some degree of release may be required to achieve complete passage of the graft. A guide wire 37 is then introduced through the anteromedial portal 16 and the tip placed at the femoral hole 29 entrance, between the edge of the hole and the tendon graft 10. The knee is then fully flexed and the guide wire 37 runs up 25mm into the tunnel between the graft 10 and the femoral hole 29 wall.

Once the surgeon is satisfied that the graft 10 and the wire 37 are correctly placed, by direct vision, a Donjoy RCI screw (made according to US Patent Application 08/039056) 38 and a driver (not shown) are run over the wire 37 and into the joint. Once the tip of the screw 38 is engaged between the graft 10 and the bone surface a firm tap with a mallet to encourage thread grip and to bed the graft down into the hole may be used, while the proximal threads 18 and the distal threads 21 on the graft 10 are kept taut, minimizing the tendency of the screw to wind up the graft 10. Then maintaining traction on the threads 18 and 21 used to hold the graft in the femoral drill hole 29, the screw 38 is advanced until the head is completely within the femoral hole 29. The head of the screw should be completely buried within the hole 29 and not visible once the screwdriver is removed. Should the screw not be advancing as it is rotated, it should again be tapped with a mallet to re-establish bony interlock and

5 Having fixed the femoral end of the tendon graft 10,
the knee is placed at 90° flexion and the tibial end 23
drawn down firmly, thereby applying tension to the
graft 10. Isometricity may be tested at this time as the
knee is extended and flexed. Having achieved the desired
10 tension and positioning of the graft 10 a guide wire 39 is
inserted between the graft and the bone of the tibia
inferiorly. While maintaining distal tension on the
graft 10, and holding the knee at 30-45° of flexion, a
screw 41 similar to screw 38 is advanced until a partial
15 grip is obtained. the knee is then gently extended
to 0° and the screw 41 then advanced fully until the
head is in the femoral hole 36 and a firm interference
grip is achieved. Full extension must be achieved prior
to completion of the insertion of the screw 41. The guide
20 wire 39 is then removed.

The motion of the knee, Lachman test, anterior draw and pivot shift test are finally checked. The knee is copiously irrigated to remove debris. A drain is passed into the joint using the arthroscopic procedure and directly laterally.

Routine closure and post-operative care is followed.